7020-02

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1050]

Certain Dental Ceramics, Products Thereof, and Methods of Making the Same

Commission Decision to Review in Part a Final Initial Determination Finding No Violation of Section 337; Schedule for Filing Written Submissions on the Issues Under Review and on Remedy, the Public Interest, and Bonding; Extension of the Target Date

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review in part the final initial determination ("final ID") issued by the presiding administrative law judge ("ALJ") on July 23, 2018, finding no violation of section 337 of the Tariff Act of 1930, in the above-captioned investigation. The Commission requests certain briefing from the parties on the issues under review, as indicated in this notice. The Commission also requests briefing from the parties, interested persons, and interested government agencies on the issues of remedy, the public interest, and bonding. The Commission has determined to extend the target date for completion of the investigation from November 23, 2018 to November 30, 2018.

FOR FURTHER INFORMATION CONTACT: Sidney A. Rosenzweig, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 708-2532. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W.,

Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server at *https://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on April 25, 2017, based on a complaint, as supplemented, filed by Ivoclar Vivadent AG of Schaan, Liechtenstein; Ivoclar Vivadent, Inc. of Amherst, New York; and Ardent, Inc. of Amherst, New York (collectively "Ivoclar"). 82 FR 19081 (Apr. 25, 2017). The complaint, as supplemented, alleged violations of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain dental ceramics, products thereof, and methods of making the same by reason of the infringement of certain claims of four United States patents: U.S. Patent No. 7,452,836 ("the '836 patent"); U.S. Patent No. 6,517,623 ("the '623 patent"); U.S. Patent No. 6,802,894 ("the '894 patent"); and U.S. Patent No. 6,455,451 ("the '451 patent"). The notice of investigation named as respondents GC Corporation of Tokyo, Japan; and GC America, Inc. of Alsip, Illinois (collectively, "GC"). The Office of Unfair Import Investigations was also named as a party.

The investigation was previously terminated as to certain asserted patent claims, including all of the asserted claims of the '623 patent and the '451 patent, based upon withdrawal of the complaint. Order No. 18 (Nov. 21, 2017), *not reviewed*, Notice (Dec. 6, 2017); Order No. 24

(Dec. 19, 2017), *not reviewed*, Notice (Jan. 18, 2018); Order No. 51 (Feb. 22, 2018), *not reviewed*, Notice (Mar. 23, 2018); Order No. 56 (Mar. 28, 2018), *not reviewed*, Notice (Apr. 27, 2018). Remaining within the scope of the investigation, as to infringement, domestic industry, or both, are claims 1, 2, 4, 5, 7, 9, 10, 13, 15-19, and 21 of the '836 patent; and claims 1, 2, 4, 16-21, 34, 36 and 38 of the '894 patent.

On July 23, 2018, the ALJ issued the final ID. The ID finds, *inter alia*, that Ivoclar failed to demonstrate infringement of the above-referenced claims of the '836 patent. The ID finds, *inter alia*, that claims 36 and 38 ("the '894 flexure strength claims") are invalid as indefinite under 35 U.S.C. § 112 ¶ 2. The ID further finds that Ivoclar failed to demonstrate infringement and failed to meet the technical prong of the domestic industry requirement as to the remaining claims of the '894 patent (claims 1, 2, 4, 5, 7, 9, 10, 13, 15-19, and 21) ("the '894 annealing claims"). The ID finds that some, but not all, of the '894 annealing claims are invalid in view of certain prior art.

Ivoclar, GC, and the Commission investigative attorney filed petitions for review and replies to the other parties' petitions.

Having reviewed the record of the investigation, including the final ID, as well as the parties' petitions for review and responses thereto, the Commission has determined as follows. The Commission has determined to review the ID's findings as to the '894 annealing claims. The Commission has determined not to review the ID's findings as to the '894 flexure strength claims because the Commission finds that the invalidity of claims 36 and 38 has been shown clearly and convincingly. The Commission has determined not to review the ID's findings for the '836

patent claims. Accordingly, the Commission finds no violation of section 337 as to the '836 patent and as to the '894 flexure strength claims. The Commission has determined not to review the remainder of the ID.

In connection with the Commission's review, the Commission notes that "[a]ny issue not raised in a petition for review will be deemed to have been abandoned by the petitioning party and may be disregarded by the Commission in reviewing the initial determination." 19 CFR 210.43(b)(2).

The parties are asked to provide additional briefing on the following issues, with reference to the applicable law and the existing evidentiary record. For each argument presented, the parties' submissions should set forth whether and/or how that argument was presented and preserved in the proceedings before the ALJ, in conformity with the ALJ's Ground Rules (Order No. 2), with citations to the record.

1. For purposes of invalidity of the '894 annealing claims, if the Commission were to find that a person of ordinary skill is entitled to rely upon the patentee's representation about the disclosure of Barrett teaching lithium disilicates, *see, e.g., PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1362 (Fed. Cir. 2007) ("Admissions in the specification regarding the prior art are binding on the patentee for purposes of a later inquiry into obviousness."), what is the role, if any, of enablement of the prior art, *see, e.g., Hoeschst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 (Fed. Cir. 2003) ("A claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled.")? Please be certain to

identify the appropriate burdens of production and persuasion, and the effect of those burdens in this investigation.

2. If the Commission finds that the sequence of steps performed by GC can practice the "annealing" limitation of the '894 annealing claims if annealing were to occur:
    a. Whether Ivoclar demonstrated, by a preponderance of evidence, that GC's methods practice the "annealing" limitation of claim 1 of the '894 patent (including all time and temperature limitations).
    b. Whether the WO196 patent application (RX-563) can be invalidating prior art, as discussed in Ivoclar's reply to GC's petition, at p. 94.
    c. Whether, to ascertain if GC's products or Ivoclar's products meet the other limitations of claim 1, or the limitations of any claim dependent upon claim 1, a remand to the presiding ALJ is warranted.

In connection with the final disposition of this investigation, the Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue one or more cease and desist orders that could result in the respondent(s) being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, USITC Pub. No. 2843, Comm'n Op.

(December 1994).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease and desist orders would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve or disapprove the Commission's action. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

Written Submissions: The parties to the investigation are requested to file combined written submissions on the issues under review and remedy, the public interest and bonding. Interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the ALJ on remedy and bonding.

The parties' submissions on the issues under review and on remedy, the public interest, and

bonding should not exceed 40 pages. Reply submissions on the issues under review should not exceed 25 pages per side. Parties are encouraged to incorporate by reference any arguments adequately presented in their petitions for review and responses thereto, rather than repeating arguments. The page limits above are exclusive of exhibits, but parties are not to circumvent the page limits by incorporating material by reference from the exhibits or from the record.

The complainants' opening submission is to include proposed remedial orders for the Commission's consideration; the date that the '894 patent expires; the HTSUS numbers under which the accused products are imported; and the names of known importers of the products at issue in this investigation.

Written submissions by the parties and the public must be filed no later than close of business on Friday, October 5, 2018. Reply submissions by the parties and the public must be filed no later than the close of business on Friday, October 12, 2018. No further submissions will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the investigation number ("Inv. No. 337-TA-1050") in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, https://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf). Persons with questions regarding filing should contact the Secretary (202-205-2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[1] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: September 21, 2018.

Lisa Barton,
Secretary to the Commission.

[1] All contract personnel will sign appropriate nondisclosure agreements.

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